

State of Montana

REPORT TO THE LEGISLATURE

Sunset Review

BOARD OF PHARMACISTS

PLEASE RETURN

The 1977 Sunset Law terminates the Board on July 1, 1981. This review provides information to assist the Legislature in making the decision to terminate, modify or continue the Board.

This report presents seven areas for Legislative consideration (page 21) including:

- ▶ The need for a state license for stores selling household medicines.
- ▶ A fund balance of \$90,000 and revenues exceeding expenditures by \$16,000 per year.
- ▶ Changes in law relative to board appointments, citizenship requirements, penalties, etc.

STATE DOCUMENTS COLLECTION

Montana 59601

Office of the Legislative Auditor
Room 135, State Capitol
Helena, Montana 59601

Montana State Library



3 0864 1003 5995 2

Office of the Legislative Auditor

STATE CAPITOL
HELENA, MONTANA 59601
406/449-3122



MORRIS L. BRUSETT, C.P.A.
LEGISLATIVE AUDITOR

February 1980

ELLEN FEAVER, C.P.A.
DEPUTY LEGISLATIVE AUDITOR
JOHN W. NORTHEY
STAFF LEGAL COUNSEL

The Legislative Audit Committee
of the Montana State Legislature:

Herein transmitted is our sunset performance review of the Montana Board of Pharmacists. The review was conducted in response to the 1977 Sunset Law, which terminates the board on July 1, 1981.

The review focused upon an examination of board operations. It does not encompass an audit of the board's financial transactions or overall compliance with state laws.

There are no formal recommendations in the report since the responsibility for such recommendations lies with the Audit Committee. Nevertheless, we discussed the contents of the report with a number of individuals and organizations, including the director of the Department of Professional and Occupational Licensing, the members of the Board of Pharmacists, the Governor's Office of Budget and Program Planning, and the Montana State Pharmaceutical Association.

We wish to express our appreciation to the members of the board and to the director of the department and

his staff for the assistance they provided during the review. We also wish to thank the members of the pharmacy profession for assistance they gave us.

Respectfully submitted,

Morris L. Brusett

Morris L. Brusett, C.P.A.
Legislative Auditor

TABLE OF CONTENTS

	<u>Page</u>
List of Illustrations	v
Appointive and Administrative Officials	vi
Chapter I	
Background	1
Report Objectives	1
Nature of the Profession	2
Chapter II	
The Board of Pharmacists	4
Board Operations	4
Structure	4
Staffing and Funding	5
Board Goals and Objectives	7
Board Functions	10
Examination	10
Licenses	10
Continuing Education	13
Complaints	13
Other Board Functions	16
Exemptions	16
Chapter III	
Other Regulation	17
Federal Regulation	17
State Regulation	18
Other States' Regulation	20

TABLE OF CONTENTS (Continued)

	<u>Page</u>
Chapter IV	
Areas for Legislative Consideration	21
Licensing Stores	22
Penalties	23
Range of Penalties	23
Conviction of a Felony	24
Fund Balance	25
Citizenship	25
Board Membership	25
Association Appointments	25
Public Membership	26
Senate Confirmation	26
Multi-Year Licensing	26
Automated License Records	27
Other Areas of Consideration	28

LIST OF ILLUSTRATIONS

<u>No.</u>		<u>Page</u>
1	Fee Schedule	6
2	Board Finances	7
3	Pass Rates for Examinations	10
4	Registered Pharmacists and Interns	11
5	Registered Pharmacies and Stores	12
6	Dangerous Drug Act Registrations	12
7	Summary of Complaints	15
8	SRS Integrity Review Results	19
9	Comparison of Pharmacist Licensing	20

APPOINTIVE AND ADMINISTRATIVE OFFICIALS
BOARD OF PHARMACISTS

		<u>Term Expires</u>
James Carlson	Miles City	1981
Terry Donahue	Butte	1980
Del Steiner	Helena	1982

DEPARTMENT OF PROFESSIONAL
AND OCCUPATIONAL LICENSING

Ed Carney	Director
Warren Amole, Jr.	Executive Secretary
Brenda Butcher	Administrative Assistant

Chapter I

BACKGROUND

This sunset performance review addresses state regulation of the pharmaceutical industry by the Board of Pharmacists (hereinafter referred to as the board), a state board within the Department of Professional and Occupational Licensing.

REPORT OBJECTIVES

The 1977 Legislature passed a law terminating numerous regulatory boards and agencies, including the Board of Pharmacists. This law, commonly referred to as the "sunset law," requires the Legislative Audit Committee to conduct a performance review of each terminated agency. The performance review must examine the need for each regulatory board/agency, and the Legislative Audit Committee must offer recommendations for board/agency reestablishment, modification, or termination.

The sunset law also requires an examination of the following questions during the conduct of the committee's review:

- (a) Would the absence of regulation significantly harm or endanger the public's health, safety, or welfare?
- (b) Is there a reasonable relationship between the exercise of the state's police power and the protection of the public's health, safety, or welfare?
- (c) Is there another less restrictive method of regulation available which could adequately protect the public?

- (d) Does the regulation have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree?
- (e) Is the increase in cost more harmful to the public than the harm which could result from the absence of regulation?
- (f) Are all facets of the regulatory process designed solely for the purpose of, and have as their primary effect, the protection of the public?

Using the information contained in this report, and that gathered during a public hearing, the committee will address these six questions. During the hearing process, testimony and comments will be heard from the board/agency, the profession, and interested members of the public.

In defining legislative intent, the sunset law states that, by requiring periodic evaluation in the form of a performance review, the legislature will be in a better position to ensure that agencies and programs exist only to be responsive to state residents' needs. The sunset law terminates the board on July 1, 1981. This sunset performance review is in response to the legal requirement for a review prior to the board's termination.

NATURE OF THE PROFESSION

The pharmacist is a health care professional specializing in the compounding and dispensing of drugs for the public. The college training and internship programs for pharmacists lead to an understanding of

how drugs can be used to treat diseases and how drugs react with each other if taken simultaneously.

Pharmacists practice in several work environments, including local pharmacies, hospitals, clinics, nursing homes, drug manufacturing firms, colleges, and government. The vast majority of pharmacists practice in local pharmacies with the next largest number working in hospitals.

The National Association of Boards of Pharmacy reports that nationwide there were approximately 130,000 active, licensed pharmacists in 1976 (the last year for which data is available). This equated to about 60 pharmacists per 100,000 population in 1976 while Montana was slightly above the national average with 63 resident pharmacists per 100,000 population in that year. One county in Montana, McCone, does not have a registered pharmacist.

Chapter II

THE BOARD OF PHARMACISTS

The 1895 Legislature created the Board of Pharmacists to regulate the quality and dispensing of drugs.

Presently, the board's functions include:

1. Licensing pharmacists.
2. Registering pharmacy interns.
3. Registering and inspecting pharmacies.
4. Registering stores which sell household medicines.
5. Registering individuals and firms which manufacture, distribute, or conduct research on controlled substances.
6. Investigating and acting on complaints against a licensee or registrant.
7. Determining which controlled substances will be made available to persons on a restricted basis.

BOARD OPERATIONS

Structure

The three-member board is appointed by the Governor from a list of five nominees supplied by the Montana State Pharmaceutical Association. The Senate does not confirm appointments. All members must be registered pharmacists and serve a three year term. Board members receive \$25 per day plus travel expenses when on board business.

The board usually meets in Missoula in January and June of each year. This site was chosen because the School of Pharmacy is located at the University of

Montana in Missoula. At those meetings, the board gives the pharmacy examinations and transacts other business. The board meets as needed at other times during the year.

Staffing and Funding

The board is attached to the Department of Professional and Occupational Licensing (DPOL) for administrative purposes. The department allocates two employees to the board. One is a full-time executive secretary who is also the pharmacy inspector. The other is an administrative assistant who spends approximately 85 percent of available time working on board business. In addition, the department supplies legal, accounting, and some additional secretarial assistance.

The executive secretary position is mandated by Montana law (section 37-7-104, MCA), which requires the department to hire a person to inspect pharmacies and stores registered by the board, to examine the records of licensees, and to assist the board in its other activities. This person must be a registered pharmacist with at least five years experience, a resident of Montana, and a citizen of the United States. The present executive secretary receives approximately \$21,000 per year to carry out these functions. In addition, the executive secretary works with the Board of Medical Examiners to examine the prescription practices of physicians. The time for such examinations is

charged to the Board of Medical Examiners. The department provides an office in Great Falls for the executive secretary and provided an office in Billings for the previous executive secretary. (In both cases, the office was in the city of residence of the executive secretary.)

The board collects fees for licenses, renewals, and examinations. Some fees are set by law and the remainder are set by the board. All fees are deposited in the earmarked revenue fund for the use of the board. Illustration 1 shows the fees charged by the board.

FEE SCHEDULE

<u>Fees Set by Law</u>	<u>Fee</u>
Pharmacist Original/Renewal License	\$ 15
Pharmacist Late Renewal	30
Reciprocity Fee	200
Store License	10
Pharmacy Original License	100
Pharmacy Late Renewal	100

Fees Set by Board

Pharmacy Renewal License	35
Change in Pharmacy Name	20
Family Planning Center	5
DDA/Manufacture or Distribute	100
DDA/Dispense	10
DDA/Analyze or Conduct Research	10
Intern Registration	15
Pharmacist Examination	35
Duplicate License	2
Certificate of Grades	5
Copies of Rules and Laws (first copy free)	5
Replacement of Original License	10

Source: Department of Professional and Occupational Licensing.

Illustration 1

The board receives all of its funds from license and registration fees. Illustration 2 shows the financial status of the board for the years 1972-1979. Fund balances are as of June 30 of each year.

BOARD FINANCES

<u>Fiscal Year</u>	<u>Revenues</u>	<u>Expenditures</u> ¹	<u>Fund Balance</u>
1978-79	\$66,325	\$50,670	\$89,830
1977-78	67,170	48,677	74,175
1976-77	63,271	50,435	55,682
1975-76	46,357	47,320	42,846
1974-75	56,952	45,638	43,809
1973-74	33,212	31,949	32,495
1972-73	45,531	29,452	31,232

¹ Includes Expenditures, Accruals, and Adjustments.

Source: Montana Financial Reports.

Illustration 2

BOARD GOALS AND OBJECTIVES

The board has stated that the following are its goals and objectives:

GOALS:

The practice of pharmacy is a professional practice affecting the health, safety and welfare and is subject to regulation and control in the public interest.

It is a matter of public interest and concern that the practice of pharmacy merit and receive the confidence of the public.

It is the board's responsibility to make certain that only qualified persons be permitted to engage in the practice of pharmacy in the state of Montana.

It is the board's responsibility to set standards of competence for the practice of pharmacy in the state of Montana.

It is the board's responsibility to assure uniform qualifications and continued competency of licensed pharmacists.

It is the board's purpose to promote, preserve, protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy.

OBJECTIVES:

In order to realize the above goals, the Board of Pharmacists shall:

License drug outlets engaged in the manufacturing, production, sale, and distribution of drugs, medications, devices and such other materials as may be used in the diagnosis and treatment of injury, illness, and disease.

Determine the minimum equipment necessary in and for a pharmacy.

Regulate, under therapeutic classification, the sale of drugs, medicines, chemicals, and poisons and their labeling.

Regulate the quality of drugs and medicines dispensed in this state, using the United States Pharmacopoeia and the National Formulary or revisions thereof as the standards.

Adopt rules necessary or proper to carry out provisions in a fair, impartial, and nondiscriminatory manner.

Assess each candidate's knowledge, skills, and abilities deemed necessary for the practice of pharmacy.

Grant license to each candidate judged to have the required proficiency for the practice of pharmacy.

Grant license to each reciprocity candidate judged to have the required proficiency for the practice of pharmacy.

Enforce the Dangerous Drug Act.

Promulgate, adopt, amend, and repeal such rules as may be deemed necessary for the proper administration and enforcement of the statutes.

Effectuate legislative mandates and decisions pertaining to the profession of pharmacy.

Inform the public of current statutes, rules and scope of the practice of pharmacy.

Determine guidelines for the expanding role of the registered pharmacist.

Participate with the National Association of Boards of Pharmacy in the publication of a quarterly newsletter containing both state and national items pertaining to changes in statutes and rules and to circulate it to all pharmacist registrants.

Make annual field checks of all certified pharmacies, registered pharmacists, registered interns, and others involved in the distribution of drugs for compliance with the statutes and rules pertaining to the practice of pharmacy.

Supervise interns and the internship program.

Participate with the School of Pharmacy in the improvement of the externship and internship programs.

Investigate all complaints registered with the board involving any registrant.

Hold hearings when deemed necessary and to dismiss charges, suspend or revoke licenses according to the evidence produced and the decision of the board.

Issue certificates of "Certified Pharmacy".

Maintain reasonable and continuing supervision and surveillance over all licensees.

Cooperate with other health-related boards to ensure that all registrants are in compliance with statutes and rules governing the practice of pharmacy.

Requiring participation in continuing pharmacy education programs as a condition for renewal of licenses.

Encourage the School of Pharmacy and the Montana State Pharmaceutical Association to provide continuing education courses for pharmacists for continued competence.

Continue to be involved in regional and national decisions affecting the practice of pharmacy in Montana.

BOARD FUNCTIONS

Examination

The board administers three examinations for persons seeking to become licensed. The National Association of Boards of Pharmacy has drafted a national exam (NABPLEX) which the board administers to all new applicants, except reciprocity applicants. In addition, the board has drafted a combination practical and jurisprudence examination for resident applicants and a jurisprudence exam for reciprocity applicants. The board requires a 75 average for passing on each examination.

PASS RATES FOR EXAMINATIONS

<u>Fiscal Year</u>	<u>NABPLEX</u>			<u>Practical/ Jurisprudence</u>		
	<u>Taken</u>	<u>Passed</u>	<u>%</u>	<u>Taken</u>	<u>Passed</u>	<u>%</u>
1978-79	35	33	94	28	28	100
1977-78	29	29	100	46	46	100
1976-77	38	35	92	44	42	95
1975-76	42	42	100	25	24	96
1974-75	26	26	100	39	34	87
1973-74	24	24	100	23	23	100
1972-73	25	25	100	27	27	100

Source: Department of Professional and Occupational Licensing.

Illustration 3

Licenses

In addition to passing the examination, the board and the legislature have established certain

educational and experience requirements. An applicant for resident licensure must be a U.S. citizen, be a graduate of an accredited school of pharmacy, and have completed a 1,500 hour internship program. The internship involves working under the supervision of a board-approved pharmacist to gain experience in all facets of the pharmacy profession. Applications for reciprocity are accepted from persons licensed in a jurisdiction which has similar requirements to Montana's. The following table shows the number of licensed pharmacists and interns.

REGISTERED PHARMACISTS AND INTERNS

<u>Fiscal Year</u>	<u>Pharmacists</u>			<u>Interns</u>
	<u>New</u>	<u>Renewed</u>	<u>Total</u>	
1978-79	63	1,055	1,118	48
1977-78	82	1,045	1,127	48
1976-77	80	1,030	1,110	48
1975-76	62	911	973	48
1974-75	49	872	921	41
1973-74	41	806	847	29
1972-73	41	846	887	25

Source: Department of Professional and Occupational Licensing.

Illustration 4

The board also registers pharmacies, stores which sell household medicines, and persons or firms which manufacture, distribute, dispense, and analyze or conduct research on controlled substances. Controlled substances include narcotics, amphetamines, and barbiturates, among other drugs. Pharmacy locations include stores, hospitals, long-term care facilities, and

family planning centers. Upon application, payment of a fee, and board approval, the board grants licenses to pharmacies, stores, and others who handle controlled substances. Stores include any business firm which sells household medicines (i.e., aspirin, cough syrup, etc.) at the retail level. The following tables summarize these registrations.

REGISTERED PHARMACIES AND STORES

<u>Fiscal Year</u>	<u>Pharmacies</u>			<u>Stores</u>		
	<u>New</u>	<u>Renewed</u>	<u>Total</u>	<u>New</u>	<u>Renewed</u>	<u>Total</u>
1978-79	21	264	285	86	1,702	1,788
1977-78	21	292	313	181	1,751	1,932
1976-77	32	321	353	590	1,227	1,817
1975-76	14	286	300	50	1,520	1,570
1974-75	NA	296	296	NA	1,645	1,645
1973-74	NA	232	232	NA	1,470	1,470
1972-73	NA	282	282	NA	1,964	1,964

NA: Not Available

Source: Department of Professional and Occupational Licensing

Illustration 5

DANGEROUS DRUG ACT REGISTRATIONS¹

<u>Year</u>	<u>New</u>	<u>Renewed</u>	<u>Total</u>
1979	21	343	364
1978	24	344	368
1977	39	344	383
1976	64 ²	339 ²	403
1975	1,454 ²	1,178 ²	2,632

¹The Dangerous Drug Act provides for the registration of all persons or firms which manufacture, distribute, dispense, and analyze or conduct research with controlled substances.

²Physicians, veterinarians, dentists, etc., were included under the original act in 1974. The 1975 Legislature repealed that provision.

Source: Department of Professional and Occupational Licensing.

Illustration 6

Continuing Education

The 1977 Legislature passed a law requiring continuing education for pharmacists. Beginning in 1980, all pharmacists must annually complete 15 hours of continuing education approved by the board to qualify for license renewal. The board is authorized to charge a fee for continuing education, but has not established such a fee.

Complaints

The board is responsible for investigating and resolving complaints against pharmacists, pharmacy interns, pharmacies, stores, or other licensees. All complaints are referred to the board executive secretary for initial screening and action. The executive secretary contacts the parties involved, investigates, and gathers information as is necessary. In some cases, the executive secretary writes letters to the alleged violator requesting that corrective action be taken. In all cases, the board is informed of the executive secretary's actions and the nature of the problem. The board then has the option of taking further action against the alleged violator.

Prior to fiscal year 1975-76, the complaint records are either missing or lack sufficient documentation for analysis. The board received 15 complaints in fiscal 1975-76, 12 in fiscal year 1976-77, 6 in fiscal year 1977-78 and 11 in fiscal year 1978-79.

These do not include investigations of physician prescription practices conducted for the Board of Medical Examiners. The following illustration summarizes the complaints received by the board.

PHARMACISTS
SUMMARY OF COMPLAINTS
FISCAL YEARS 1975-76 TO 1978-79

<u>Type of Complaint</u>	<u>Number</u>	<u>Source of Complaint</u>	<u>Resolution</u>
Unprofessional or Illegal Conduct by Pharmacist	18	Consumer	Letter Requesting
		Board	Corrective Action
			Investigated - No
		Other	Evidence of Problem
		Not Apparent	Deferred Suspension*
		From File	Surrendered License
			None**
Unprofessional or Illegal Conduct by Other Professional	3	Pharmacist	Letter Requesting
		Other	Corrective Action
			Referred to Board of Medical Examiners
Intern Working Without Proper Supervision	4	Board	Letter Requesting
		Other	Corrective Action
			None**
Improper Advertisement By Store Not Licensed As a Pharmacy	4	Board	Requested to Stop
		Not Apparent	Advertisements
		From File	None**
Incorrect Prescriptions Given to Consumers	2	Consumer	Letter Requesting
			Corrective Action
Unlicensed Person Filling Prescriptions	9	Consumer	Letter Requesting
		Board	Action
		Not Apparent	Investigated - No
		From File	Evidence
Other***	4	Board	Letter Requesting
		Other	Corrective Action
		Not Apparent	Investigated - No
		From File	Evidence
Total	44	Consumer	Letter Requesting
		Board	Corrective Action
		Other	Investigated - No
		Not Apparent	Evidence
		From File	Referred to Board of Medical Examiners
		Pharmacist	Deferred Suspension
			Surrendered License
			None**

* See the discussion on page 16.

** No evidence of action in the complaint file.

***Includes such things as pharmacists no longer supervising hospital pharmacy, no regular hours for pharmacy, request to stock controlled substances, etc.

Source: Compiled by the Office of the Legislative Auditor

Illustration 7

The one suspension of a licensee in the last four years occurred in fiscal year 1978-79. A pharmacist was convicted in federal court of not keeping adequate records and was given a suspended sentence. The board then suspended the license but deferred the imposition of the suspension if the pharmacist did not violate a law or rule for the next year. Another licensee surrendered a license after pleading guilty to several violations of federal drug laws.

Other Board Functions

Since 1975, the board has published a monthly flyer which is sent to each licensee. The flyer contains items of interest to pharmacists concerning board activities and federal and state regulations.

EXEMPTIONS

The law exempts duly licensed physicians, dentists, and veterinarians from regulation by the board. The Dangerous Drug Act originally required these medical practitioners to be licensed by the board, but was amended to exclude such persons from registration the following year.

In addition, drugs, chemicals, or poisons for commercial use, insecticides and fungicides, and common household preparations not used for medicinal purposes are exempt from regulation by the board.

Chapter III

OTHER REGULATION

FEDERAL REGULATION

Two federal agencies are involved with the control of drugs. The Drug Enforcement Administration (DEA) of the U.S. Department of Justice licenses all persons and firms involved in the manufacture, distribution, and dispensing of drugs. It also determines which drugs are to be classified as controlled substances. The Food and Drug Administration (FDA) of the U.S. Department of Health, Education and Welfare determines which drugs are safe for public use.

DEA licenses all persons or firms which manufacture, distribute, or dispense controlled substances. It also licenses medical practitioners (i.e., doctors, dentists, podiatrists, etc.) who prescribe or dispense drugs. The board also licenses persons and firms which manufacture, distribute, or dispense controlled substances. The only difference between DEA and board licensing is that the board does not license medical practitioners. The DEA license for pharmacies is based on the state licensing process. A pharmacy which holds a valid certified pharmacy license and which has not been involved in a drug related crime normally receives a DEA license automatically.

In addition, the Drug Enforcement Administration determines what drugs will be classified as controlled

substances, while the board is charged by Montana law with much the same task. The board executive secretary and a Drug Enforcement Administration official stated that presently the board uses the schedule of controlled substances classified by the Drug Enforcement Administration. These controlled substances include narcotics, amphetamines, and barbituates, among other drugs.

STATE REGULATION

On the state level, two agencies, the Economic Assistance Division of the Department of Social and Rehabilitation Services (SRS) and the Hospital and Medical Facilities Division of the Department of Health and Environmental Sciences (HES), are involved with pharmacies and pharmacists.

The Economic Assistance Division distributes state Medicaid money. Part of these funds may be paid to pharmacists for prescriptions. Prescription reimbursement is based on the cost of the drugs plus the cost of filling the prescription. SRS audits two percent of each pharmacy's claims for payment. If irregularities are found, SRS can suspend a pharmacist from participation in the program. SRS has performed at least 60 integrity reviews on pharmacies since 1974. The following table categorizes those actions.

SRS INTEGRITY REVIEW RESULTS

<u>Enforcement Action</u>	<u>Number</u>
Warning Letter	6
Provider Suspended	4
Request for Recovery of Funds	1
Funds Recovered	12
Case Referred to Law Enforcement	4
Closed No Referral	2
Criminal Conviction or Civil Action	1
Facts Insufficient for Further Investigation	26
Referred to Department of Revenue	2
None Listed	9

Note: Some reviews may have more than one action associated.

Source: SRS Integrity Review Log.

Illustration 8

As part of HES's hospital and medical facility inspections are examinations of the facility's pharmacy. The facility's license is partially dependent on its pharmacy conforming to HES rules. HES rules for hospital and medical facility pharmacies were almost identical to those which the board established for the same type of facility. Recently, however, HES and the board have revised their rules to eliminate overlapping responsibilities.

OTHER STATES' REGULATION

Regulation of pharmacists in Montana is similar to that of the other 49 states and the District of Columbia. Illustration 9 shows a comparison of Montana's regulation with that of other jurisdictions.

Comparison of Pharmacist Licensing

<u>Item</u>	<u>Nationwide</u> (50 states plus DC)	<u>Montana</u>
Licensing Entity	Board of Pharmacists 51	Board of Pharmacists
Public Members	Yes 14 No 37	No
Citizenship or Intent	Yes 17 No 34	Yes
Graduate of College of Pharmacy	Yes 51	Yes
Internship	Yes 51	Yes
National Exam	Yes 51	Yes
Length of Renewal	Annual 36 Biennial 15	Annual

Source: Compiled by the Office of the Legislative Auditor.

Illustration 9

Chapter IV

AREAS FOR LEGISLATIVE CONSIDERATION

The design and effectiveness of certain aspects of the regulatory process may warrant legislative consideration. The intent of the following sections is to briefly discuss these aspects as they apply to pharmacists. The areas for consideration include:

1. Licensing stores.
2. Penalties.
3. Fund balance.
4. Citizenship.
5. Board membership.
6. Multi-year licensing.
7. Automated license records.
8. Other areas of consideration.

In addition to the above aspects, we noted several other areas that warranted consideration. We discussed these areas with the board and the board subsequently took action. The following summarizes the concern and the board action:

1. The board had two rules which unduly restricted pharmacy operations. One set a maximum number of hours a pharmacist could work per week if the individual was not the store owner. The other required the president and one officer of a corporation which owned a pharmacy to be registered pharmacists before a license would be granted to the pharmacy. Neither rule provided much additional public protection. An overworked "owner-operator" would probably make no fewer mistakes than a pharmacist who simply works in a store, and the board already required the person who supervises a pharmacy be

licensed. The board removed both restrictions.

2. The board and HES were both inspecting hospital and long-term care facility pharmacies for basically the same requirements. The board and HES changed their rules to reduce duplication in inspection requirements.
3. One board rule prohibited the dispensing of all drugs, even aspirin and cough drops, by vending machine. Public protection was not greatly enhanced since these household drugs could be obtained on a pick-up basis in grocery and other stores, which is virtually the same as dispensing from vending machines. The board changed the rule to apply only to prescription drugs.
4. Part of the records of the board were kept in the Great Falls office of the executive secretary. This was in violation of Montana law which requires all board records be kept in Helena. The records have been transferred to Helena.
5. Several of the fees charged by the board (including the pharmacist examination and the intern registration fees) were not specified in either the law or the rules. The board amended its rules to include all of its fees.
6. The board did not have a log of complaints and many complaints were kept together in a single file folder. Without a log and individual files for complaints, it was difficult to fully trace the course of a complaint. The board has established a complaint log and is keeping individual files on complaints.

LICENSING STORES

Presently, Montana law requires all stores which sell any household medicines, such as aspirin, cough syrup, etc., to be registered with the board. This registration requires the filing of a simple, one-page form and the payment of a \$10 fee. These fees generate nearly \$20,000 in annual revenue for the board. One

board member commented that the reason for the law is to generate revenue for the board while another doubted the need for store licenses.

The board does not systematically review stores for compliance with this statute. In a cursory review of grocery stores in the Helena area, we noted six which sold household medicines but were not licensed by the board. While this law generates a great deal of revenue for the board, it is doubtful that public protection is greatly enhanced by the current administration of the law.

PENALTIES

Range of Penalties

Presently, the board has the power to suspend or revoke a license, but lacks the explicit power to take other disciplinary action. A study by the Council of State Governments and the Federal Trade Commission indicates that many regulatory boards will not take action against a licensee because the penalty for the violation is more severe than the violation warrants. While possible additional disciplinary measures (including reprimands, probationary licenses, and practice restriction on licenses) are implied, explicit authorization may be warranted.

A person who violates any of the provisions of Parts 1 through 3 of the pharmacy law (the licensing of

pharmacists, pharmacies, and stores) commits a misdemeanor, but the law does not provide a specific penalty. Therefore, a court may imprison a person for up to 6 months and/or a fine not to exceed \$500.

Montana law provides that anyone who is convicted of a violation of Parts 1 through 3 of the pharmacist law automatically loses his license. This does not allow the board to consider the severity of the violation or other mitigating circumstances when it determines the action to be taken against a person's license.

Conviction of a Felony

Montana's pharmacy law provides for the revocation, suspension, or denial of a pharmacist, pharmacy, or store license for the conviction of any felony. In contrast, section 37-1-203, MCA, states that no person may be refused a license simply on the basis of a criminal conviction. Only the conviction of a crime directly related to the licensed activity can serve as the basis for such a refusal. Article II, Section 28 of Montana's Constitution provides that a person will have full rights restored after the termination of state supervision for any offense against the state. These two laws and this constitutional provision are inconsistent. The pharmacy law should be amended to resolve the inconsistency.

FUND BALANCE

The board's fund balance has more than doubled in the last six years with revenues exceeding expenditures in five of the six years. For fiscal year 1978-79, the revenues exceeded expenditures by more than \$16,000 and the fund balance was nearly twice the expenditures. The board should reexamine its fee structure to assure that it only collects the revenue it needs to carry out regulation. If the store license were repealed, the revenues and expenditures would be more nearly equal.

CITIZENSHIP

Montana's law requires that a person must be a United States citizen before being licensed in the state of Montana. The United States Supreme Court (McLaughlin vs. Florida 379 U.S. 184 and Sugarman vs. Dugal 413 U.S. 63) declared that such citizenship requirements are unconstitutional.

BOARD MEMBERSHIP

Association Appointments

The Governor is required by law to appoint each member of the board from a list of nominees supplied by the Montana Pharmaceutical Association. The association represents approximately 65 percent of the state's pharmacists. This limits the latitude of the Governor in making appointments of board members. In addition, the Supreme Courts in two other states, Washington and South Carolina, have struck down similar provisions as unconstitutional delegations of authority.

Public Membership

In order to facilitate public input into board operations, some states have required that regulatory boards have public members. Fourteen states have at least one public member on the board which regulates pharmacy. All the board members and the executive secretary favor the idea of public membership.

Senate Confirmation

Gubernatorial appointments to the board are not subject to Senate confirmation. The Senate confirms the appointments to some of the state's boards and commissions. In addition, during the 1977-79 biennium of sunset, the Legislative Audit Committee recommended that appointments to additional regulatory boards be subject to Senate confirmation.

MULTI-YEAR LICENSING

The administrative assistant for the board spends a significant amount of time notifying licensees that their licenses are due for renewal and then processing those renewals. One alternative to this expenditure of time every year is to spread the renewals over two or more years.

If license renewals are spread over more than one year, this will reduce the workload for the department. In the case of biennial licensing, only half as many licenses must be processed in a given year. Fifteen states currently have biennial license renewals for pharmacists.

With continuing education, biennial licensing demands that double the number of hours be earned for each renewal. This should not be burdensome to the licensee since there will be more flexibility in earning those hours. Further, the goal of maintaining competency among licensees should not be adversely affected because the two year period is short enough that the licensee must keep relatively current.

Multi-year licensing would create savings in administrative expenses. The amount saved would depend upon the number of licensees renewing each year. In order to maintain a level of income consistent with administrative expenses, the renewal fee as established may have to be increased from the current annual renewal fee. Due to a potential reduction in costs, the renewal fee for a biennial renewal, for example, would not necessarily have to be double the current fee.

AUTOMATED LICENSE RECORDS

All records on licensees are kept manually. In addition, each new or renewed license must be manually typed by the administrative secretary. An alternative is to automate the licensee records. The automated system could print the renewal notices and also the licenses. Further, such automated records could be used to generate statistical reports on the licensee population. Additions and deletions to the licensee files could be made relatively easily.

OTHER AREAS OF CONSIDERATION

In previous reviews of regulatory boards in Montana, the aspect of uniformity among boards in reimbursement of board members was often discussed. This issue was not addressed in this review since the reimbursement amount for members of the Board of Pharmacists is similar to that of other regulatory boards.

